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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

HINES, JANA A

ART UNIT PAPER NUMBER

1645

15

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/464,158

Applicant(s)

SUNDREHAGEN

Examiner

Ja-Na Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on December 9, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 13-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 9, 2002 has been entered.

Amendment Entry

2. The amendment filed December 9, 2002 has been entered. The specification and claims 1-12 have been amended. Claims 13-17 have been newly added.

Election/Restrictions

3. Newly submitted claims 13-17 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The method for detecting an indicator of alcohol abuse and associated kit is an unrelated method. This method has a different use, i.e., to indicate alcohol abuse. Furthermore, this method requires different steps, i.e., forming a conjugate and detecting the presence of the transferrin by turbidometry or nephelometry techniques. The method of originally presented group does not produce the same results. Each group produces different

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effects and different functions when compared to the other group. Therefore, the inventions are unrelated.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 13-17 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

4. Claims 1-12 are under consideration in this office action.

Withdrawal of Rejections

5. The rejection of claims 3 and 5 under 35 U.S.C. 112, second paragraph, is withdrawn.

Response to Arguments

6. Applicant's arguments filed December 9, 2002 have been fully considered but they are not persuasive.

7. The rejection of claims 1-12 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps is maintained. There are no steps recited in the method which recite how the determination of the content of carbohydrate-free transferrin in said sample and thereby

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determining the content of carbohydrate-free transferrin in said sample would create a use in the assessment of elevated alcohol consumption.

Moreover, it is still unclear how one skilled in the art will determine the content of carbohydrate-free transferrin without some form of detection step. Simply separating the unbound fraction will not determine the content of carbohydrate-free transferrin. Without the recitation of a detection step, one cannot be reasonably apprised of the method steps in this method claim. The specification teaches the use of many methods requiring a detection step, thus the claims must positively recite these same steps. Therefore, the rejection is maintained.

Applicants argue that because their methods are versatile in that they can be considered flexibility so that the methods are amenable to differences available in the art, the additional steps are readily apparent. However this argument is not persuasive, since the claims as recited are incomplete and amount to a gap between the steps.

New Grounds of Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 3 and 5 are drawn to groups consisting of "mixtures thereof". The written description in this case only sets forth specific carbohydrate-binding ligands; therefore the written description is not commensurate in scope with the claims drawn to mixtures thereof. Neither the claims nor the specification teach how to obtain such mixtures thereof. There is no guidance as to what the mixtures are; or what ligands can or cannot be used in the mixture being claimed. The specification does not include structural examples of mixtures thereof, but rather only teaches combinations. Thus, the resulting mixtures thereof could result in mixtures not taught and enabled by the specification.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

With the exception of specifically named ligands, the skilled artisan cannot envision the detailed structure of the mixtures thereof, thus conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. An adequate description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it.

Furthermore, *In The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of by only their functional activity does not provide an adequate description of the genus. The court indicated that while Applicants are not required to disclose every species

encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of molecules falling within the scope of the claimed genus.

It is noted that combinations of ligands is different than mixtures thereof. As argued by applicant with respect to the ordinary meaning of mixture; there is no teaching of a portion of matter consisting of two or more components in varying proportions that retain their own properties. Therefore, despite applicants' arguments to the contrary, mixtures thereof is not supported by the specification.

Therefore only the recited carbohydrate binding ligands and not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph.

9. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preamble of the claims are drawn to a method for the determination of carbohydrate-free transferrin in a body fluid for use in the assessment of elevated alcohol consumption, however there are no steps within the method which teach how to use the determination in the assessment of elevated alcohol consumption. The claims lack a positive recitation of method steps that recite how to use the determination in the assessment of elevated alcohol consumption. Therefore, the goal of the preamble is not commensurate with the steps of the method of determination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. The rejection of claims 1-3, 6-8 and 10-12 under 35 U.S.C. 102(b) as being anticipated by Sundrehagen (WO 91/19983) is maintained for reasons of record. The rejection was on the grounds that Sundrehagen teaches assessing the concentration of a subset of analyte variants within a group of different analyte variants, test kits and reagents composition for use in such method. The assessment of the level of different transferrin in serum is of particular importance because transferrin in chronic alcohol abusers has a desialylated transferrin isoform. This transferrin carries two or less sialyl residues, is relatively increased in content when compared to non-alcoholics and is called Desialylated transferrin or Carbohydrate Deficient Transferrin (CDT).

Again applicant urges that Sundrehagen does not teach or suggest carbohydrate free transferrin (CFT) and that CDT contains some carbohydrate containing transferrin moieties. However, it is still the examiner's position that the CDT of Sundrehagen teaches the invention as described by the instant application. The specification at page 7 beginning at line 14 defines CFT as a transferrin which does not carry at least 60% or more carbohydrate chains, thus the CDT of Sundrehagen meets the limitations of the claims. The definition by the specification is not limited to transferrin molecules having no carbohydrate side chains like applicants' assert. Moreover, applicant merely states the conclusion that CDT does not meet the limitations of the claims without providing any scientific evidence. Thus the argument is not persuasive and the claims remain rejected.

Applicants argue that it is not necessary to use the fractionation step disclosed by Sundrehagen to obtain transferrin isoforms separation in the present invention and the precipitation can be used. However, it is noted that the claims are not limiting in the manner necessary to obtain transferrin isoforms. Therefore, Sundrehagen is still applicable.

The MPEP section 2123 teaches that patents are relevant as prior art for all they contain, "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir.1998) (The court held that the prior art anticipated the claims even though it taught away from the claimed invention. "The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed."). Therefore applicant's argument is not persuasive especially when considering applicants argument that it is not necessary to use fractionation methods when the instant claims require similar and functionally equivalent techniques.

Applicants assert that the separation step in the claims distinguishes over Sundrehagen. However, Sundrehagen teaches a separation step wherein separation can occur by centrifugation or filtration if the solid phase is in slurry batch form or by magnetic separation if the solid anion exchange phase is magnetizable or by elution (page 13 lines 7-13). See also Figure 1 which clearly teaches a separation step after binding the ligands to labeled antibody. Therefore, applicants' assertion is not persuasive.

Applicants argue that the kit is distinguished over the prior art because of the separation step, however, it is the examiner's position that Sundrehagen teaches the same structural means supplied by the instant kit which have the same function. Therefore, this argument is not persuasive and there are no distinguishing differences between the prior art and instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The rejection of claims 4-5 under 35 U.S.C. 103(a) as being unpatentable over Sundrehagen (WO 91/19983) in view of Pikelharing et al., (Analytical Biochem) is maintained for reasons already of record. Sundrehagen (WO 91/19983) has been discussed above. However, the rejection was on the grounds that it would have been obvious at the time of applicants invention to use a modified ELISA by replacing the immobilized antibody or enzyme linked antibody with a lectin or other carbohydrate

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binding protein of Pekelharing et al., (Analytical Biochem) in the method of assessment of alcohol consumption as taught by Sundrehagen, because Pekelharing et al., teach that the use of lectins increases the speed, specificity, sensitivity and simplicity of an immunoassay.

Applicants assert that the basis for obviousness is conclusory since neither teach a method for the determination of CFT in a body fluid and therefore teach away from the invention.

The preamble language of the instant claims does not result in a structural difference. If the prior art is capable of performing the intended use, then it meets the claim. In this case the prior art is capable of performing the intended function. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Moreover, it is the examiner's position that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). The invention was directed to an epoxy impregnated fiber-reinforced printed circuit material. The applied prior art reference taught a printed circuit material similar to that of the claims but impregnated with polyester-imide resin instead of epoxy. The reference, however, disclosed that epoxy was known for this use, but that epoxy impregnated circuit boards have "relatively acceptable dimensional stability" and "some degree of flexibility," but are inferior to

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circuit boards impregnated with polyester-imide resins. The court upheld the rejection concluding that applicant's argument that the reference teaches away from using epoxy was insufficient to overcome the rejection since "Gurley asserted no discovery beyond what was known in the art." 27 F.3d at 554, 31 USPQ2d at 1132. Therefore contrary to applicants' argument, the prior art does not teach away from the instant claims.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one having ordinary skill in the art would have been motivated to make such a change such as a alternative and functionally equivalent modified ELISA since only the expected results would have been obtained. The prior art clearly teaches replacing the immobilized antibody or enzyme linked antibody with a lectin or other carbohydrate binding protein to create a heterologous lectin-enzyme immunoassay system, therefore, a skilled artisan would have had a reasonable expectation of success in switching the lectin. The use of an alternative technique would have been desirable to those of ordinary skill in the art based on the fact that the modified immunoassay has increased sensitivity when subfractions are quantitated; increases the captured protein; increases binding affinity; and increases speed, specificity and simplicity when microtiter plates are used. The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the

literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir.1998). Therefore applicants arguments are not persuasive and the rejection is maintained.

12. The rejection of claim 9 under 35 U.S.C. 103(a) as being unpatentable over Sundrehagen (WO 91/19983) in view of Dreher et al., Canadian Patent 2,074,345 is maintained for reasons already of record. The rejection was on the grounds that no more than routine skill would have been required to use well known methods for transferrin determination using immunoturbidimetry and immunonephelometry techniques as taught by Dreher et al., in the method of assessment of transferrin as taught by Sundrehagen, because Dreher et al., teach that immunoturbidimetry and immunonephelometry techniques can be easily and simply automated.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

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In response to applicant's general argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, it would have been prima facie obvious to modify the method of Sundrehagen (WO 91/19983) to incorporate determination using turbidometric or nephelometric means because Dreher et al., teach that immunoturbidimetry and immunonephelometry techniques can be easily used and simply automated. One would have a reasonable expectation of success since the techniques are based on interactions between antibodies and detected antigen, which Sundrehagen already teaches. Moreover, the turbidometric and nephelometric means have already been used in the prior art to determine transferrin content. Therefore, one having ordinary skill would have been motivated to make such a change as a mere alternative and functionally equivalent detection means since only the expected effects would have been obtained. The prior art clearly teaches the detection of transferrin, therefore a skilled artisan would have had a reasonable expectation of success in exchanging the determination techniques. Moreover, the use of alternative and functionally equivalent determination techniques would have been desirable to those of ordinary skill in the art based on ease and previous performance of said techniques.


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Thus, applicants' arguments are not persuasive and the rejection is maintained.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines 
February 19, 2003


LYNETTE R. F. SMITH
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